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K001844

Special 510(k) - Line Extension
Summary of Safety and Effectiveness for the
Kyphotic and Lordotic Plates of the Centaur™ Spinal System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Team Member

Date of Summary Preparation:

June 5, 2000

Device Identification

Proprietary Name:

Centaur™ Spinal System

Common Name:

Spinal Fixation Appliance

Classification Name and Reference:

Spinal Interlaminal Fixation Orthosis
21 CFR §888.3050

Predicate Device Identification

The features of the kyphotic and lordotic plates of the Centaur™ Spinal System are substantially equivalent to the features of the straight plates of the Centaur™ Spinal System which were determined substantially equivalent via K994347.

Device Description

The Centaur™ Spinal System is a spinal fixation device for the noncervical spine. All components are manufactured from titanium alloy (Ti6Al-4V ELI) which conforms to ASTM F-136-96. The subject plates are all L-shaped. The lordotic plates range from 60mm to 90mm in length in 10mm increments. The kyphotic plates range in length from 50mm to 90mm in 10mm increments. The plate system is not monoblock, thereby allowing more flexibility and greater opportunity for compression which aids fusion. Plates are assembled to the screws through the use of a plate connector and are locked down by set screws.

Intended Use:
The subject kyphotic and lordotic plates are intended for use with the Centaur™ Spinal System. Specific indications for the Centaur™ Spinal System follow.

When used as an anterior, thoracic/lumbar screw fixation system, the Centaur™ Spinal System is intended to treat deformities of curvature (i.e. scoliosis, kyphosis and/or lordosis), fracture, tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e.discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Statement of Technological Comparison:
The kyphotic and lordotic plates of the Centaur™ Spinal System share the same intended use and basic design concepts as the straight plates of the Centaur™ Spinal System. An engineering analysis and mechanical testing using representative plates demonstrate the safety and effectivess of the subject components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

Ms. Elizabeth A. Staub
V.P.- Quality Assurance/Regulatory Affairs/Clinical Research
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K001844
Trade Name: Centaur Spinal System – Kyphotic and Lordotic Plates
Regulatory Class: II
Product Code: KWQ
Dated: June 5, 2000
Received: June 19, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001844

Device Name: Lordotic and Kyphotic Plates, Centaur™ Spinal System

The Kyphotic and Lordotic Plates are intended to be used as part of the Centaur™ Spinal System.

Indications For Use:

- When used as an anterior, thoracic/lumbar screw fixation system, the Centaur™ Spinal System is intended to treat deformities of curvature (i.e. scoliosis, kyphosis and/or lordosis), fracture, tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e.discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use YES OR Over-The-Counter Use NO

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Donna R. Bochner

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K001844